

1K 121156

**ThermoFisher**  
SCIENTIFIC

1 (3)

**MAR 13 2013**

**510(k) Summary**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

**Premarket Notification 510(k) No:**

**Date of Summary Preparation:** April 12, 2012

**Distributor:** Phadia US Inc.  
4169 Commercial Avenue  
Portage, MI 49002  
269-492-1957

**Manufacturer:** Phadia AB  
Rapsgatan 7P  
P.O. Box 6460  
751 37 Uppsala, Sweden

**Company Contact Person:** Martin Mann  
Regulatory Affairs Manager  
Phadia US Inc.  
4165 Commercial Avenue  
Portage, MI 49002  
269-492-1957

**Device Names:**

- ImmunoCAP Allergen f236, Cow's milk whey
- ImmunoCAP Allergen f309, Chick pea
- ImmunoCAP Allergen t212, Cedar
- ImmunoCAP Allergen t222, Cupressus arizonica

**Common Name:**

Automated in vitro quantitative assay for the measurement of allergen specific IgE antibodies.

**Classification:**

<u>Product Name</u>	ImmunoCAP Allergen Components
<u>Product Code</u>	DHB
<u>Class</u>	II
<u>CFR</u>	866.5750

**Substantial Equivalence to:**

ImmunoCAP Specific IgE	(k051218)
UniCAP 100	(k962274)

**Indications For Use Statement**

ImmunoCAP Specific IgE is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, and Phadia 1000. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

**Device Description****Reagents**

ImmunoCAP Specific IgE reagents are modular in concept and are available individually. For a complete listing of reagents needed to perform the Phadia ImmunoCAP Specific IgE assay, please consult the ImmunoCAP Specific IgE Conjugate Directions for Use.

**Instrument System**

Phadia 100, Phadia 250 and Phadia 1000 instruments with built-in software process all steps of the assay and print results automatically after the assay is completed.

**ImmunoCAP Specific IgE, Test Principle**

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient sample. After washing away non-specific IgE, enzyme labeled antibodies against IgE are added to form a complex. After incubation, unbound enzyme-anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The higher the response value, the more specific IgE is present in the specimen. To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve.

**Performance characteristics**

The new ImmunoCAP Allergens were characterized with the use of clinical positive samples, as well as samples from healthy, non-atopic donors. The performance characteristics of the new ImmunoCAP Allergens were established through studies of Precision, including Lot-to-Lot Reproducibility, Linearity and Limit of Detection. Inhibition studies verified the immunological specificity of the allergens.

**Conclusion**

The safety and effectiveness of the cleared device ImmunoCAP Specific IgE system for the determination of specific IgE antibodies have been established in previous 510(k) submissions. This submission covers the addition of 4 new ImmunoCAP Allergens to the existing ImmunoCAP Specific IgE assay. No changes are made to the Intended Use or in the Indications for Use statements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center-- WO66-G609  
Silver Spring, MD 20993-0002

Phadia AB  
c/o Mr. Martin Mann  
Regulatory Affairs Manager  
4169 Commercial Avenue  
Portage, MI 49002 US

March 13, 2013

Re: k121156

Trade/Device Name: ImmunoCAP Specific IgE  
ImmunoCAP Allergen f236, Cow's milk whey  
ImmunoCAP Allergen f309, Chick pea  
ImmunoCAP Allergen t212, Cedar  
ImmunoCAP Allergen t222, Cupressus arizonica  
Regulation Number: 21 CFR § 866.5750  
Regulation Name: Radioallergosorbent (RAST) immunological test system  
Regulatory Class: Class II  
Product Code: DHB  
Dated: March 5, 2013  
Received: March 8, 2013

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.  
Director  
Division of Immunology and Hematology Devices  
Office of *In Vitro* Diagnostics and Radiological  
Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if Known): **k121156**

**Device Name:** ImmunoCAP Specific IgE

### Indications for Use:

ImmunoCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, and Phadia 1000. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

**Maria M. Chan -S**

---

Division Sign-Off

Office of In Vitro Diagnostics  
and Radiological Health

510(k)\_k121156\_\_\_\_\_